

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Remarks

Amendment to the Claims

Claims 11-34 have been amended. Claims 11-15 were amended to refer to a formulation comprising a population of nanoparticles. Support for this amendment can be found in the specification at least at page 22, lines 12-13 and 25. . The original claim list omitted claim 16. Claims 17-34 have been amended to correct this numbering error. Former claim 20 (now claim 19) was amended to correct a typographical error by inserting a space between "11" and "comprising". Former claim 31 (now claim 30) was further amended to eliminate multiple dependencies and to insert the limitations of claim 11.

Response to Restriction Requirement

In the Office Action mailed December 21, 2006, the Examiner divided the claims into three groups, Group I, claims 1-10, drawn to a method for preparing nanoparticles; Group II, claims 11-30, drawn to a formulation of nanoparticles, and Group III, claims 31-34, drawn to a method for treating a patient.

In response, Applicants elect Group II, claims 11-30 (renumbered as claims 11-29), with traverse. Groups II and III should be grouped together. Groups II and III contain claims defining a product and a process of using the product, respectively. According to M.P.E.P. § 806.05 (b), product and process of using the product are grouped together unless (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. Neither of these conditions is met.

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Claim 11 defines a formulation comprising a population comprising at least 95% nanoparticles of a therapeutic, diagnostic or prophylactic agent having a diameter of less than one micron; and claim 31 (renumbered as claim 30) defines a method for treating a patient by administering the formulation defined by claim 11. Thus the method requires the use of the formulation defined by claim 11. Similarly, claim 11 requires the inclusion of a therapeutic, diagnostic or prophylactic agent, which can only be used in a method requiring the step of administering the formulation to a patient. Accordingly, the claims in Groups II and III should be grouped together. Reconsideration of the Restriction requirement is respectfully solicited.

Election of Species

The Office Action also required the election of a species of an agent, a bioadhesive enhancing agent, a dispersant, a polymer encapsulating agent, a surfactant, an excipient, and a polymer. In response, Applicants elect small-molecule drugs for the agent, bioadhesive organic molecules for the bioadhesive enhancing agent, polyvinyl pyrrolidone for the dispersant, TWEENs® for the surfactant, a tabletting agent for the excipient, and poly(lactic acid) for both the polymer and the polymer encapsulating agent. Claims 11-34 (renumbered as 11-33) read on the elected species. Claims 11-34 (renumbered as 11-33) are generic to Group II.

Applicants make this species election with the understanding that upon a finding that the elected species are patentable, the generic claims will be fully searched and examined.

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Favorable consideration of claims 11-33, as renumbered and amended, is respectfully solicited.

Respectfully submitted,

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